

**GUIDE FOR REVIEWERS' PRELIMINARY COMMENTS
ON NATIONAL RESEARCH SERVICE AWARD (NRSA)
PREDOCTORAL FELLOWSHIP APPLICATIONS (F31)
SUPPORTED BY NIMH, NIDA, NIAAA, NIDCD, NIDCR AND NCCAM**

This individual predoctoral fellowship award (F31) is designed to train future generations of outstanding scientists committed to pursuing a career in mental health, drug abuse, and/or alcohol abuse and alcoholism research. The review of an application should focus on the following: the applicant, the research training plan, the sponsor, and the institutional environment/commitment. Information from the letters of reference should be used to inform considerations of these factors, and the final priority score should reflect the overall evaluation of the entire application.

REVIEW FORMAT

APPLICANT:

The applicant's potential for, and commitment to, a productive scientific career. The reviewers may take into account the applicant's history as a student, as well as past and current involvement in research activities.

RESEARCH TRAINING PLAN:

objectives, design, and direction of the proposed research program;

specificity and clarity of the description of the research skills and knowledge to be acquired;

overall coherence and potential of the research training plan to provide the fellow with individualized supervised experiences that will develop research skills;

clarity, completeness, originality, and significance of the goals of the proposed research training plans;

adequacy of knowledge of relevant literature and current methods in the proposed research area;

adequacy of plans for the protection of human subjects, animals, or the environment, to the extent they may be adversely affected by the research proposed;

adequacy of plans to include women, children and minorities as subjects in research, if applicable;

adequacy of plans to provide training in the responsible scientific conduct of research.

SPONSOR:

caliber of the sponsor as a researcher, including successful competition for research support;

evidence of the proposed sponsor's understanding of and commitment to fulfilling the role of sponsor and mentor;

evidence of an understanding of the applicant's research training needs and a demonstrated ability, on the part of the sponsor, to assist in meeting those needs;

past research training record of the sponsor in terms of the rate at which former predoctoral trainees obtain their doctoral degree and go on to postdoctoral or other scientific careers.

INSTITUTIONAL ENVIRONMENT/COMMITMENT:

training environment including the institutional commitment to research training and career development, the quality of the facilities and related resources (e.g., equipment, laboratory space, computer time, subject populations) and the availability of research support.

OTHER CONSIDERATIONS

Foreign Training: In a separate section, describe the scientific advantages of the proposed training in a foreign country and compare it to relevant training opportunities available in this country. Comment on any special talents, resources, populations, or environmental conditions that are not readily available in the United States or that augment existing resources. This consideration should not be factored into your overall recommendation and rating.

Protection Of Human Subjects From Research Risks: If the application involves human subjects, evaluate the application with reference to the following criteria: risk to subjects, adequacy of protection against risks, potential benefit to the subjects and to others, importance of the knowledge to be gained. (If the applicant fails to address **all** of these elements, notify the SRA immediately to determine if the application should be withdrawn.) If all of the criteria are adequately addressed, and there are no concerns. Write "Acceptable Risks and/or Adequate Protections." A brief explanation is advisable. If one or more criteria are inadequately addressed, write, "Unacceptable Risks and/or Inadequate Protections" and document the actual or potential issues that create the human subjects concern. If the application indicates that the proposed human subjects research is exempt from coverage by the regulations, determine if adequate justification is provided. If the claimed exemption is not justified, indicate "Unacceptable" and explain why you reached this conclusion. Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRA immediately to determine if the application should be withdrawn.) Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

Gender, Minority And Children Subjects: Public Law 103-43 requires that women and minorities must be included in all NIH-supported clinical research projects involving

human subjects unless a clear and compelling rationale establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. NIH requires that children (individuals under the age of 21) of all ages be involved in all human subjects research supported by the NIH unless there are scientific or ethical reasons for excluding them. Each project involving human subjects must be assigned a code using the categories "1" to "5" below. Category 5 for minority representation in the project means that only foreign subjects are in the study population (no U.S. subjects). If the study uses both then use codes 1 thru 4. Examine whether the minority and gender characteristics of the sample are scientifically acceptable, consistent with the aims of the project, and comply with NIH policy. For each category, determine if the proposed subject recruitment targets are "A" (acceptable) or "U" (unacceptable). If you rate the sample as "U", consider this feature a weakness in the research design and reflect it in the overall score. Explain the reasons for the recommended codes; this is particularly critical for any item coded "U".

Category	Gender (G)	Minority (M)	Children (C)
1	Both Genders	Minority & non-minority	Children & adults
2	Only Women	Only minority	Only children
3	Only Men	Only non-minority	No children included
4	Gender Unknown	Minority representation unknown	Representation of children unknown
5		Only Foreign Subjects	

NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under "Research Proposal" in the major review criteria above, and should be factored into the score as appropriate.

Animal Welfare: Express any comments or concerns about the appropriateness of the responses to the five required points, especially whether the procedures will be limited to those that are unavoidable in the conduct of scientifically sound research.

Biohazards: Note any materials or procedures that are potentially hazardous to research personnel and indicate whether the protection proposed will be adequate.

The program announcement associated with this specific fellowship award can be found at <http://grants.nih.gov/grants/guide/pa-files/PA-99-017.html>

Further general information about NIH research training opportunities can be found at <http://grants.nih.gov/training>